

Rochester, NY 14603-1051

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

DATE MAILED: 07/31/2006

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/790,456 03/01/2004		David S. Goldfarb	176/61481 9599 (1-11027-03034)		
7:	590 07/31/2006	EXAMINER			
Edwin V. Merkel			SCHLAPKOHL, WALTER		
Nixon Peabody	LLP				
Clinton Square			ART UNIT	PAPER NUMBER	
P.O. Box 31051		1636			

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.		Applicant(s	Applicant(s)				
		10/790,45	6	GOLDFARB, DAVID S.					
Office Action Summary			Examiner A		Art Unit				
			Walter Sch	lapkohl	1636	waf			
Period fo	The MAILING DATE of this commun or Reply	ication app	ears on the	cover sheet with	the corresponden	ce address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
Status									
1)⊠	Responsive to communication(s) file	ed on <i>01 Ma</i>	arch 2004.						
	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.								
•—	Since this application is in condition	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
,	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Dispositi	ion of Claims								
4)⊠ Claim(s) <u>1-58</u> is/are pending in the application.									
•	4a) Of the above claim(s) is/are withdrawn from consideration.								
	5) Claim(s) is/are allowed.								
	6) Claim(s) is/are rejected.								
	☐ Claim(s) is/are objected to.								
8)⊠	Claim(s) 1-58 are subject to restricti	ion and/or e	election req	uirement.					
Applicati	on Papers								
9) ☐ The specification is objected to by the Examiner.									
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.									
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).									
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).									
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority ι	ınder 35 U.S.C. § 119								
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some colon None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>									
Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  4) Interview Summary (PTO-413) Paper No(s)/Mail Date  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152) 6) Other:									

## DETAILED ACTION

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I-LVII. Claims 1-12, 16-23, 26 and 27-28, drawn to a method of identifying a gene that alters the lifespan of an organism as the claims read on one galactose responsive promoter (GAL1, GAL7 or GAL10) in combination with one cell cycle protein (CDC2, CDC3, CDC4, CDC6, CDC7, CDC8, CDC9, CDC10, CDC13, CDC16, CDC20, CDC23, CDC24, CDC26, CDC27, CDC28, CDC34, CDC42 or CDC53), classified in class 435, subclass 29.
- LVIII. Claims 1-3, 13-14, 16-23 and 27-28, drawn to a method of identifying an environmental stimulus that alters the lifespan of an organism, classified in class 435, subclass 29.
- identifying a gene and an environmental stimulus that alters the lifespan of an organism as the claims read on one galactose responsive promoter (GAL1, GAL7 or GAL10) in combination with one cell cycle protein (CDC2, CDC3, CDC4, CDC6, CDC7, CDC8, CDC9, CDC10,

CDC13, CDC16, CDC20, CDC23, CDC24, CDC26, CDC27, CDC28, CDC34, CDC42 or CDC53) and one human homolog (RAS, BAX, SIR2, WRN or BS), classified in class 435, subclass 29.

CCCXLV-DCXXX. Claims 30-46 and 48-57, drawn to a DNA construct comprising a first and second chimeric gene drawn to one galactose responsive promoter (GAL1, GAL7 or GAL10) in combination with one cell cycle protein (CDC2, CDC3, CDC4, CDC6, CDC7, CDC8, CDC9, CDC10, CDC13, CDC16, CDC20, CDC23, CDC24, CDC26, CDC27, CDC28, CDC34, CDC42 or CDC53), and further drawn to a kit comprising yeast with such a DNA and further comprising one gene promoting shortened lifespan (RAS, BAX, SIR2, WRN or BS), classified in class 435, subclass 254.2.

DCXXXI. Claim 58, drawn to a method of identifying quantitative trait loci for aging-related genes in yeast, classified in class 435, subclass 29.

The inventions are distinct, each from the other, for the following reasons:

Page 4

Art Unit: 1636

of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different polynucleotides/polypeptides which do not render each other obvious and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific polynucleotide/polypeptide combination to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the polynucleotides/polypeptides are different and distinct and thus the methods drawn to different and distinct polynucleotides/polypeptides are different and distinct inventions from each other.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct combinations of polynucleotides and polypeptides, followed by an election of a single invention drawn to one combination of polynucleotides or polypeptides within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

For related process inventions, the inventions are distinct if (a) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; (b) the inventions as claimed are not obvious variants; and (c) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect. See MPEP § 802.01. The methods of Groups I-LVII, Group LVIII, Groups LVIX-CCCXLIV and Group DCXXXI do not overlap in scope because the Group I-LVII inventions comprise identifying genes that alter lifespan, whereas the Group LVIII invention comprises identifying an environmental stimulus that alters lifespan, whereas the Group LVIX-CCCXLIV inventions comprise identifying both genes and environmental stimuli that alter lifespan of an organism, whereas the Group DCXXXI invention comprises identification of quantitative trait loci for aging-related Furthermore, the Group I-LVII, Group LVIII, Group LVIX-CCCXLIV and Group DCXXXI inventions have a materially different design, mode of operation and/or effect since they comprise methods of identification utilizing mother cells with genotype modification only (Groups I-LVII), mother cells exposed to environmental stimulus (Group LVIII), mother cells with genotype modification as well as exposure to environmental stimulus

(Groups LVIX-CCCXLIV) and yeast strains with different replicative lifespans (Group DCXXXI). Moreover the Group I-LVII, Group LVIII, Group LVIX-CCCXLIV and Group DCXXXI inventions are not obvious variants because, for example, the determination of quantitative loci for aging-related genes in yeast (as in Group DCXXXI) is not an obvious variation over the identification of a gene that alters the lifespan of an organism (as in Groups I-LVII).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions of Groups I-LVII, Group LVIII, Groups LVIX-CCCXLIV & Group DCXXXI and inventions of Groups CCCXLV-DCXXX are related as processes and products for their practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed

can be used to practice another and materially different (MPEP § 806.05(e)). In this case the processes as claimed can be practiced by utilizing any of the Group CCCXLV-DCXXX inventions. For example, the Group II invention could be practiced by assaying with a yeast cell comprising the DNA construct of Invention CCCXLV (comprising GAL1 and CDC2) and further comprising a RAS gene or with a yeast cell comprising the DNA construct of Invention CDIV (comprising GAL1 and CDC3 and further comprising a BAX gene. Similarly, the CCCXLV-DCXXX inventions could be utilized to practice methods for identifying environmental stimuli that alter the lifespan of an organism as in the LVIX-CCCXLIV inventions or in a method for identifying quantitative trait loci as in the Group DCXXXI invention. Furthermore, the Group LVIII invention can be practiced with yeast cells not comprising the DNA construct or without kit components of the Group CCCXLV-DCXXX inventions, but rather with mother yeast cells that are exposed to an environmental stimulus.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Page 8

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Claims 29 and 47 link inventions CCCXLV-DCXXX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 29 and 47. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

Application/Control Number: 10/790,456

Art Unit: 1636

prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species which apply if Applicant elects on of the Group I-LVII, Group LVIII or Group LVIX-CCCXLIV inventions:

- 1) a method for identifying a gene or environmental stimulus that alters the lifespan of an organism wherein the determining comprises performing growth curve analyses (claims 16-18); and
- 2) a method for identifying a gene or environmental stimulus that alters the lifespan of an organism wherein said determining comprises assessing colony size (claims 19-23).

The species are independent or distinct because the claims encompass method steps which are not present in or required for the practice of the invention(s) from which they depend.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the

claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Page 11

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election

must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

Page 13

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

Application/Control Number: 10/790,456 Page 14

Art Unit: 1636

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D. Patent Examiner Art Unit 1636

July 12, 2006

PRIMARY EXAMINER